IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CYDEX PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, LTD. and ALEMBIC PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff CyDex Pharmaceuticals, Inc. ("CyDex"), by its undersigned attorneys, brings this action against Defendants Alembic Pharmaceuticals, Ltd. ("APL"), Alembic Global Holding SA ("Alembic Global"), and Alembic Pharmaceuticals, Inc. ("Alembic Inc."), (collectively, "Alembic" or "Defendants"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States arising from the submission of Abbreviated New Drug Application No. 212810 (the "Alembic ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of EVOMELA® (Captisol®-enabled Melphalan HCl) for Injection, 50 mg/vial.

THE PARTIES

2. Plaintiff CyDex Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 3911 Sorrento Valley Boulevard, Suite 110, San Diego, CA 92121.

3. CyDex is informed and believes, and thereon alleges, that Defendant Alembic Pharmaceuticals, Ltd. ("APL") is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

4. CyDex is informed and believes, and thereon alleges, that APL controls and directs a wholly owned subsidiary named Alembic Global Holding SA ("Alembic Global"). Alembic Global is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland.

5. CyDex is informed and believes, and thereon alleges, that Alembic Global controls and directs a wholly owned subsidiary in the United States named Alembic Pharmaceuticals, Inc. ("Alembic Inc."). Alembic Inc. is a Delaware corporation having a principal place of business at 750 Route 202, Bridgewater, New Jersey 08807.

6. CyDex is informed and believes, and thereon alleges, that APL is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of Delaware, through its own actions and through the actions of its agents and subsidiaries, including Alembic Global and Alembic Inc., from which APL derives a substantial portion of its revenue.

7. CyDex is informed and believes, and thereon alleges, that APL acted in concert with Alembic Global and Alembic Inc. to prepare and submit ANDA No. 212810 ("the Alembic ANDA") for Melphalan hydrochloride for injection (the "Alembic ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of APL. Following FDA approval of the Alembic ANDA, APL will manufacture and supply the approved generic product

to Alembic Global and/or Alembic Inc., which will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of APL.

JURISDICTION AND VENUE

8. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 101, *et seq.,* seeking a finding and declaratory judgment of patent infringement under 35 U.S.C. § 271(e)(2)(A) and the remedies provided under the Hatch-Waxman Act specified in 35 U.S.C. § 271(e)(4). Jurisdiction exists under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and venue is proper in this Court under 28 U.S.C. §§ 1400(b) and/or 1391(c).

9. Venue is proper in this Court because, among other things, Alembic Inc. is incorporated in the State of Delaware and therefore "resides" in this judicial district. 28 U.S.C. § 1400(b). APL and Alembic Global are foreign corporations not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c).

10. CyDex is informed and believes, and thereon alleges, that APL develops, manufactures, and/or distributes generic drugs for sale or use throughout the United States, including in this judicial district.

11. CyDex is informed and believes, and thereon alleges, that this Court has personal jurisdiction over APL because, *inter alia*, APL: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute the Alembic ANDA Product to residents of this State upon approval of ANDA No. 212810, either directly or through at least one of its wholly-owned subsidiaries or agents; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through Alembic Inc., which is a Delaware

corporation; and (4) owns Alembic Global, which owns Alembic Inc., which is a Delaware corporation.

12. Alternatively, CyDex is informed and believes, and thereon alleges, that this Court may exercise jurisdiction over APL pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) APL would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) APL has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products through its U.S. subsidiaries that are distributed throughout the United States, such that this Court's exercise of jurisdiction over APL satisfies due process.

13. CyDex is informed and believes, and thereon alleges, that Alembic Global develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

14. CyDex is informed and believes, and thereon alleges, that, this Court has personal jurisdiction over Alembic Global because, *inter alia,* Alembic Global: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its parent, wholly-owned subsidiaries, or agents; (2) intends to market, sell, and/or distribute the Alembic ANDA Products to residents of this State upon approval of the Alembic ANDA, either directly or through at least one of its parent, wholly-owned subsidiaries, or agents; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through Alembic Inc., which is a Delaware corporation; and (4) owns Alembic Inc., which is a Delaware corporation.

15. Alternatively, CyDex is informed and believes, and thereon alleges, that this Court may exercise jurisdiction over Alembic Global pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Alembic Global would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Alembic Global has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products through its U.S. subsidiaries that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alembic Global satisfies due process.

16. CyDex is informed and believes, and thereon alleges, that Alembic Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

17. CyDex is informed and believes, and thereon alleges, that this Court has personal jurisdiction over Alembic Inc. because, *inter alia,* Alembic Inc.: (1) is incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute Alembic's ANDA Products to residents of this State; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

THE PATENTS-IN-SUIT

18. On December 1, 2015, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued United States Patent No. 9,200,088 ("the '088 patent"), entitled "Sulfoalkyl Ether Cyclodextrin Compositions." A true and correct copy of the '088 patent is attached hereto as Exhibit A.

19. On November 15, 2016, the USPTO duly and lawfully issued United States Patent No. 9,493,582 ("the '582 patent"), entitled "Alkylated Cyclodextrin Compositions and Processes

for Preparing and Using the Same." A true and correct copy of the '582 patent is attached hereto as Exhibit B.

20. CyDex Pharmaceuticals is the owner of all right, title, and interest in the '088 patent and the '582 patent (collectively, "the patents-in-suit").

EVOMELA®

21. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the patents-in-suit are listed in the FDA publication entitled *Approved Drug Products and Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with FDA-approved New Drug Application ("NDA") No. 207155 as covering EVOMELA® (Captisol®-enabled Melphalan HCl) for Injection; 50mg (free base)/vial.

THE ALEMBIC ANDA

22. On April 9, 2019, CyDex received a letter from Alembic Global Holdings SA, dated April 8, 2019, regarding "Notification of Paragraph IV Certification Pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" ("Alembic's Purported Notice Letter"). Alembic's Purported Notice Letter states that Alembic submitted an ANDA to the FDA under 21 U.S.C. § 355(j)(1) and (2)(A), seeking FDA approval to manufacture, offer to sell, and sell a generic version of EVOMELA®.

23. Alembic's Purported Notice Letter identifies that Alembic filed the Alembic ANDA.

24. CyDex is informed and believes, and thereon alleges, that the Alembic ANDA was submitted to the FDA for approval to market a generic version of EVOMELA® prior to the expiration of the patents-in-suit.

25. CyDex is informed and believes, and thereon alleges, that upon FDA approval of the Alembic ANDA, Defendants will market and distribute the Alembic ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the Alembic ANDA Product. CyDex is informed and believes, and thereon alleges, that the Alembic ANDA refers to and relies upon the EVOMELA® NDA and contains data that, according to Alembic, demonstrate the required bioavailability and/or bioequivalence of the Alembic ANDA Product and EVOMELA®.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,200,088

26. CyDex realleges and incorporates by reference the allegations of paragraphs 1-25 of this Complaint as if fully set forth herein.

27. Defendants infringed the ’088 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Alembic ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Alembic ANDA Product prior to the expiration of the ’088 patent.

28. Defendants’ commercial manufacture, use, offer to sell, or sale of the Alembic ANDA Product within the United States, or importation of the Alembic ANDA Product into the United States, during the term of the ’088 patent also would infringe the ’088 patent under 35 U.S.C. § 271(a), (b), (c), (f) and/or (g).

29. Defendants’ commercial manufacture, use, offer to sell, or sale of the Alembic ANDA Product within the United States, or importation of the Alembic ANDA Product into the United States, during the term of the ’088 patent, would infringe at least Claim 1 of the ’088 patent because, CyDex is informed and believes, and thereon alleges, that the Alembic ANDA Product contains a sulfoalkyl ether cyclodextrin (SAE-CD) composition that can be readily

mixed with an active agent, comprising a sulfoalkyl ether cyclodextrin having an average degree of substitution of 4.5 to 7.5 and less than 200 ppm of a phosphate, wherein the SAE-CD composition has an absorption of less than 0.5 A.U. due to a UV-active impurity as determined by UV/vis spectrophotometry at a wavelength of 245 nm to 270 nm for an aqueous solution containing 300 mg of the SAE-CD composition per mL of solution in a cell having a 1 cm path length.

30. Upon approval of the Alembic ANDA, and the commercial marketing of the Alembic ANDA Product, Defendants would actively induce and/or contribute to infringement of the ’088 patent.

31. CyDex is informed and believes, and thereon alleges, that, at least in light of the prescribing instructions Defendants propose to provide in connection with the Alembic ANDA Product, Defendants will induce health care professionals, resellers, pharmacies, and end users of the Alembic ANDA Product to directly infringe one or more claims of the ’088 patent. CyDex is informed and believes, and thereon alleges, that Defendants will encourage acts of direct infringement with knowledge of the ’088 patent and knowledge that they are encouraging infringement.

32. CyDex is informed and believes, and thereon alleges, that Defendants had actual and constructive knowledge of the ’088 patent prior to filing the Alembic ANDA, and were aware that the filing of the Alembic ANDA with the request for FDA approval before the expiration of the ’088 patent would constitute an act of infringement of the ’088 patent.

33. Defendants have no reasonable basis for asserting that the commercial manufacture, use, sale, offer for sale, or importation of the Alembic ANDA Product will not contribute to the infringement and/or induce the infringement of the ’088 patent.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 9,493,582

34. CyDex realleges and incorporates by reference the allegations of paragraphs 1-33 of this Complaint as if fully set forth herein.

35. Defendants infringed the '582 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Alembic ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Alembic ANDA Product prior to the expiration of the '582 patent.

36. Defendants' commercial manufacture, use, offer to sell, or sale of the Alembic ANDA Product within the United States, or importation of the Alembic ANDA Product into the United States, during the term of the '582 patent also would infringe the '582 patent under 35 U.S.C. § 271(a), (b), (c), (f) and/or (g).

37. Defendants' commercial manufacture, use, offer to sell, or sale of the Alembic ANDA Product within the United States, or importation of the Alembic ANDA Product into the United States, during the term of the '582 patent, would infringe at least Claim 27 of the '582 patent because, CyDex is informed and believes, and thereon alleges, that the Alembic ANDA Product contains an alkylated cyclodextrin composition, comprising: an alkylated cyclodextrin having an average degree of substitution of 2 to 9; less than 500 ppm of a phosphate; and 0.07% (w/w) or less of a chloride; wherein the alkylated cyclodextrin composition has an absorption of less than 1 A.U., as determined by UV/vis spectrophotometry at a wavelength of 245 nm to 270 nm for an aqueous solution containing 300 mg of the alkylated cyclodextrin composition per mL of solution in a cell having a 1 cm path length.

38. Upon approval of the Alembic ANDA, and the commercial marketing of the Alembic ANDA Product, Defendants would actively induce and/or contribute to infringement of the '582 patent.

39. CyDex is informed and believes, and thereon alleges, that, at least in light of the prescribing instructions Defendants propose to provide in connection with the Alembic ANDA Product, Defendants will induce health care professionals, resellers, pharmacies, and end users of the Alembic ANDA Product to directly infringe one or more claims of the '582 patent. CyDex is informed and believes, and thereon alleges, that Defendants will encourage acts of direct infringement with knowledge of the '582 patent and knowledge that they are encouraging infringement.

40. CyDex is informed and believes, and thereon alleges, that Defendants had actual and constructive knowledge of the '582 patent prior to filing the Alembic ANDA, and were aware that the filing of the Alembic ANDA with the request for FDA approval before the expiration of the '582 patent would constitute an act of infringement of the '582 patent.

41. Defendants have no reasonable basis for asserting that the commercial manufacture, use, sale, offer for sale, or importation of the Alembic ANDA Product will not contribute to the infringement and/or induce the infringement of the '582 patent.

EXCEPTIONAL CASE

42. This case is exceptional, and CyDex is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

INJUNCTIVE RELIEF

43. CyDex will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the patents-in-suit.

44. CyDex has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, CyDex prays for a judgment in its favor and against Defendants, and respectfully requests the following relief:

A. A judgment that Defendants have infringed one or more claims of the ’088 patent under 35 U.S.C. § 271(e)(2) by submitting the Alembic ANDA to the FDA;

B. A judgment that Defendants have infringed one or more claims of the ’582 patent under 35 U.S.C. § 271(e)(2) by submitting the Alembic ANDA to the FDA;

C. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g), Defendants’ commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Alembic ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the ’088 patent;

D. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g), Defendants’ commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Alembic ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the ’582 patent;

E. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Defendants, their affiliates and subsidiaries, and all persons and entities acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, or importing into the United States the Alembic ANDA Product within the United States, or importing the Alembic ANDA Product into the United States, until the expiration of the ’088 and ’582 patents.

F. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 212810 shall be no earlier than the last expiration date of any of the '088 and '582 patents, or the expiration date of any applicable exclusivity;

G. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alembic ANDA Product, or any product that infringes the '088 patent, or induces or contributes to such conduct, prior to the expiration of the '088 patent;

H. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alembic ANDA Product, or any product that infringes the '582 patent, or induces or contributes to such conduct, prior to the expiration of the '582 patent;

I. A judgment that this is an exceptional case under 35 U.S.C. § 285, and awarding CyDex its reasonable attorneys' fees;

J. An award to CyDex of its costs and expenses in this action; and

K. Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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